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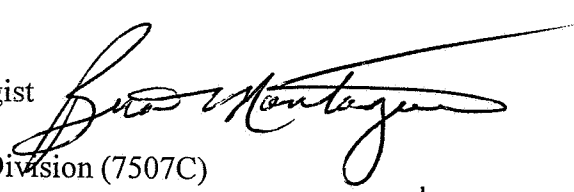
OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

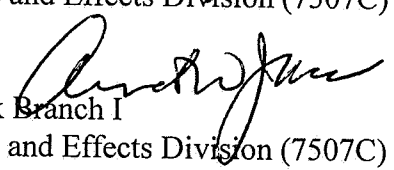
APR 25 2000

MEMORANDUM

SUBJECT: Review of Metolachlor (CGA 51202) - Shaughnessy Code 108801
Studies Submitted under Barcodes D260006, D260007, D260009, D260010 and
Submission Numbers S569370, S569375, S569376, S569377

TO: Betty Shackleford, Product Manager⁵³
Reregistration Division (7508C)

From: Brian Montague, Fisheries Biologist
Environmental Risk Branch I
Environmental Fate and Effects Division (7507C) 

Through: Arnet Jones, Chief
Environmental Risk Branch I
Environmental Fate and Effects Division (7507C)  04/25/2000

The Environmental Fate and Effects Division has completed review of 7 studies with metolachlor identified as CGA 51202. Unfortunately in most of these studies the purity of the test material was not properly identified. Two of the acute studies with fish were found invalid (44929501 and 44929502) due to departures from accepted Agency test methodology. The study with *Daphnia magna* (MRID 44929503) was found supplemental with results showing low toxicity to this species ($EC_{50} = 15.4$ ppm) from this test material. The study with the alga *Scenedesmus subspicatus* (MRID 44929515) was only conducted for 3 days, is not generally an accepted species, and test material purity was unidentified, thus classifying this study as supplemental data. The acute test with *Lemna gibba* (MRID 44929514) was classified as core and the observed EC_{50} of >95.4 ppm would place this chemical in the category of practically non-toxic to this species. Tier I terrestrial plant studies (MRID 44929513) with the chemical were considered core, as test levels equivalent to the maximum reported rate of 0.5 lbs ai/A caused $< 25\%$ growth or phytotoxic effect to seedlings or early emergent plants for the 10 tested species.

Questions regarding this memorandum and the results of these studies may be directed to Brian Montague at 305-6438 or Arnet Jones at 305-7416.

DATA EVALUATION RECORD
§ 72-1 - ACUTE LC₅₀ TEST WITH A COLDWATER FISH

1. **CHEMICAL:** Metolachlor PC Code No.: 108801
2. **TEST MATERIAL:** CGA-51202 Purity: Not reported
3. **CITATION:** Author: A. Vial
Title: Report on the Acute Toxicity Test of CGA-51202 to Rainbow Trout (*Onchorhynchus mykiss*)
Study Date: August 12, 1991
Laboratory: Ciba-Geigy Limited, Crop Protection Division, Basle, Switzerland
Sponsor: Novartis Crop Protection, Inc., Greensboro, NC
Laboratory ID: 918150
MRID No.: 449295-01
DP Barcode: D260006

4. **REVIEWED BY:** Karl Bullock, M.S., Environmental Scientist,
Golder Associates Inc.

Signature:

Date:

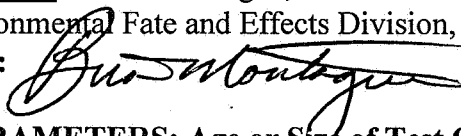
APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist,
Golder Associates Inc.

Signature:

Date:

5. **APPROVED BY:** Brian Montague, Fisheries Biologist
Environmental Fate and Effects Division, OPP

Signature:



Date: March 2000

6. **STUDY PARAMETERS:** Age or Size of Test Organism: Mean: 57 mm
Definitive Test Duration: 96 hours
Study Method: Static
Type of Concentrations: Mean measured

7. **CONCLUSIONS:** This study is scientifically sound but does not fulfill Agency guideline requirements for an acute toxicity test with the rainbow trout. The 96-hour LC₅₀ was determined to be >100 ppm nominal (>96.3 ppm mean measured concentration), which classifies CGA-51202 as practically non-toxic to the rainbow trout. The NOEC was 100 ppm nominal (96.3 ppm mean measured concentration).

Results Synopsis

LC₅₀: >100 ppm

(>96.3 ppm mean measured)

95% C.I.: N/A

NOEC: 100 ppm

Probit Slope: N/A

8. ADEQUACY OF THE STUDY:

- A. **Classification:** Invalid
- B. **Rationale:** The purity of the test substance was not reported. De-chlorinated water was employed.
- C. **Repairability:** No

9. GUIDELINE DEVIATIONS:

1. The percent purity of the test substance was not reported.
2. Dilution water was dechlorinated tap water.
3. Temperature was not measured continuously as recommended by the guidelines. The test temperature (14°C) was greater than recommended (12°C).
4. Pretest mortality was not reported.
5. Test solutions were aerated during the test.

10. SUBMISSION PURPOSE: Submitted to support registration of metolachlor products.

11. MATERIALS AND METHODS:**A. Test Organisms**

Guideline Criteria	Reported Information
<u>Species</u> Preferred species is the rainbow trout (<i>Oncorhynchus mykiss</i>)	<i>Oncorhynchus mykiss</i>
<u>Mean Weight</u> 0.1-5 g	Mean: 1.71 g Range: 1.02-2.50 g
<u>Mean Standard Length</u> Longest not > 2x shortest	Mean: 57 mm Range: 50-63 mm
<u>Supplier</u>	P. Hohler/CH-4314 Zeiningen
All fish from same source?	Yes
All fish from the same year class?	Not reported

B. Source/Acclimation

Guideline Criteria	Reported Information
<u>Acclimation Period</u> Minimum 14 days	48 days
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	Not reported
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	Fish were treated with 0.15 mg malachite green/L for 5 hours on April 6, 1991, approximately 6 weeks before test initiation.
<u>Feeding</u> No feeding during the study	Last fed 24 hours prior to testing
<u>Pretest Mortality</u> < 3% mortality 48 hours prior to testing	Not reported

C. Test System

Guideline Criteria	Reported Information
<u>Source of dilution water</u> Soft reconstituted water or water from a natural source, not dechlorinated tap water	Carbon filtered, dechlorinated tap water.
Does water support test animals without observable signs of stress?	Yes
<u>Water Temperature</u> 12°C	14°C
<u>pH</u> Prefer 7.2 to 7.6	7.6 - 8.3
<u>Dissolved Oxygen</u> Static: ≥ 60% during 1 st 48 hrs and ≥ 40% during 2 nd 48 hrs, flow-through: ≥ 60%	≥90% during the test

Guideline Criteria	Reported Information
<u>Total Hardness</u> Prefer 40 to 200 mg/L as CaCO ₃	164 mg/L as CaCO ₃
<u>Test Aquaria</u> 1. <u>Material</u> : Glass or stainless steel 2. <u>Size</u> : Volume of 18.9 L (5 gal) or 30 x 60 x 30 cm 3. <u>Fill volume</u> : 15-30 L of solution	Glass 20 L 15 L
<u>Type of Dilution System</u> Must provide reproducible supply of toxicant	Not reported but test assumed to be static test.
<u>Flow Rate</u>	Not applicable if static test
<u>Biomass Loading Rate</u> Static: ≤ 0.8 g/L at $\leq 17^{\circ}\text{C}$, ≤ 0.5 g/L at $> 17^{\circ}\text{C}$; flow-through: ≤ 1 g/L/day	0.57 g/L
<u>Photoperiod</u> 16 hours light, 8 hours dark	16 h light, 8 h dark
<u>Solvents</u> Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests	Solvent: none Maximum conc.: N/A

D. Test Design

Guideline Criteria	Reported Information
<u>Range Finding Test</u> If $\text{LC}_{50} > 100$ mg/L with 30 fish, then no definitive test is required.	Pretests were conducted, but the results were not reported.

Guideline Criteria	Reported Information
<p><u>Nominal Concentrations of Definitive Test</u> Control & 5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be in a geometric series</p>	Negative control, 10, 18, 32, 58, and 100 mg/L, not corrected for percent purity.
<p><u>Number of Test Organisms</u> Minimum 10/level, may be divided among containers</p>	10 fish per treatment level or control, 5 per replicate
<p>Test organisms randomly or impartially assigned to test vessels?</p>	Not reported
<p>Biological observations made every 24 hours?</p>	Yes
<p><u>Water Parameter Measurements</u> 1. <u>Temperature</u> Measured constantly or, if water baths are used, every 6 hrs, may not vary > 1°C 2. <u>DO and pH</u> Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control</p>	Temperature, DO, and pH were measured daily in each test chamber.
<p><u>Chemical Analysis</u> Needed if solutions were aerated, if chemical was volatile, insoluble, or known to absorb, if precipitate formed, if containers were not steel or glass, or if flow-through system was used</p>	Samples were collected from each test vessel at test initiation and termination for analysis.

12. REPORTED RESULTS:**A. General Results**

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes, however, the compliance was with OECD and Swiss GLP.
<u>Recovery of Chemical</u> 1. Mean recovery 2. Detection limit 3. Method validation	1. 91-99% of nominal 2. <1.0 mg/L 3. 108% of nominal
<u>Control Mortality</u> Not more than 10% control organisms may die or show abnormal behavior.	0% mortality in control
Raw data included?	Yes
Signs of toxicity (if any) were described?	No signs of test material toxicity were observed.

Analytical Results

Toxicant Concentration (mg/L)				
Nominal	Hour of Study		Mean Measured (SD)	Percent of Nominal
	0	96		
Control	<1	<1	-	-
10	9.90	8.30	9.10 (1.1)	91
18	17.80	16.70	17.3 (0.8)	96
32	29.10	29.20	29.2 (0.1)	91
58	57.10	57.20	57.2 (0.1)	99

100	98.60	93.90	96.3 (3.3)	96
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Mortality

Concentration (mg/L)		Number of Fish	Cumulative Number Dead			
Nominal	Mean Measured		Hour of Study			
			24	48	72	96
Negative Control	<0.10	10	0	0	0	0
10	9.10	10	0	0	0	0
18	17.3	10	0	0	0	0
32	29.2	10	0	0	0	0
58	57.2	10	0	0	0	0
100	96.3	10	0	0	0	0

Other Significant Results: No sublethal signs of test material toxicity were observed.

B. Statistical Results

Statistical method: Visual observation using nominal concentrations

LC₅₀: >100 mg/L

95% C.I.: N/A

Probit Slope: N/A

NOEC: 100 mg/L

13. VERIFICATION OF STATISTICAL RESULTS:

Parameter	Result
Binomial Test LC ₅₀ (95% C.I.)	N/A
Moving Average Angle LC ₅₀ (95% C.I.)	N/A

Probit LC ₅₀ (95% C.I.)	N/A
Probit Slope	N/A
NOEC	100 ppm

14. **REVIEWER'S COMMENTS:** This study is scientifically sound but does not fulfill the EPA criteria requirements for a fully acceptable acute toxicity test with the rainbow trout. The percent active ingredient of the test substance was not reported and de-chlorinated tap water was employed. Several other omissions of data regarding test organisms and test methods were also noted. Based on nominal concentrations, the 96-hour LC₅₀ was determined to be >100 ppm (>96.3 ppm mean measured concentration), which classifies CGA-51202 as practically non-toxic to the rainbow trout. The NOEC was 100 ppm (96.3 ppm mean measured concentration). This study is classified as **invalid**.

DATA EVALUATION RECORD
§ 72-1 - ACUTE LC₅₀ TEST WITH A WARMWATER FISH

1. **CHEMICAL:** Metolachlor PC Code No.: 108801
2. **TEST MATERIAL:** CGA-51202 Purity: Not reported
3. **CITATION:** Author: A. Vial
Title: Report on the Acute Toxicity Test of CGA-51202 to Common Carp (*Cyprinus carpio*)
Study Completion Date: August 12, 1991
Laboratory: Ciba-Geigy Limited, Crop Protection Division, Basle, Switzerland
Sponsor: Novartis Crop Protection, Inc., Greensboro, NC
Laboratory Report ID: 918151
MRID No.: 449295-02
DP Barcode: D260006
4. **REVIEWED BY:** Karl Bullock, M.S., Environmental Scientist,
Golder Associates Inc.

Signature:

Date: 11/99

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist,
Golder Associates, Inc.

Signature:

Date:
5. **APPROVED BY:** Brian Montague, Fisheries Biologist
Environmental Fate and Effects Division, OPP

Signature:

Date: March 2000
6. **STUDY PARAMETERS:** Age or Size of Test Organism: 32-43 mm
Definitive Test Duration: 96 hours
Study Method: Static
Type of Concentrations: Mean measured
7. **CONCLUSIONS:** This study is scientifically sound but does not fulfill Agency guideline requirements. The 96-hour LC₅₀ for carp exposed to CGA-51202 was determined to be >100 ppm nominal (>93.1 ppm mean measured), which classifies this compound as practically non-toxic to the carp.
Results Synopsis
LC₅₀: >100 ppm nominal (>93.1 mean measured) 95% C.I.: N/A
NOEC: 100 ppm nominal
8. **ADEQUACY OF THE STUDY:** A. **Classification:** Invalid

B. Rationale: The percent purity of the test substance was not reported. Study was conducted with de-chlorinated tapwater. See deviations below.

C. Repairability: No.

9. GUIDELINE DEVIATIONS:

1. The percent purity of the test material was not reported.
2. The test was conducted with a species other than the recommended species.
3. Dilution water was dechlorinated tap water.
4. Pretest mortality was not reported.
5. Test solutions were aerated.

10. SUBMISSION PURPOSE: To support reregistration of metolachlor.

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
<u>Species</u> Preferred species is the bluegill sunfish (<i>Lepomis macrochirus</i>)	Carp, <i>Cyprinus carpio</i>
<u>Mean Weight</u> 0.5-5 g	Mean: 0.74 g Range: 0.41-0.96 g
<u>Mean Standard Length</u> Longest not > 2x shortest	Mean: 39 mm Range: 32-43 mm
<u>Supplier</u>	P. Hohler / CH-4314 Zeiningen
All fish from same source?	Yes
All fish from the same year class?	Not reported

B. Source/Acclimation

Guideline Criteria	Reported Information
<u>Acclimation Period</u> Minimum 14 days	24 days

Guideline Criteria	Reported Information
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	Not reported
Feeding No feeding during the study	Last fed 24 hours prior to testing
Pretest Mortality < 3% mortality 48 hours prior to testing	Pretest mortality not reported

C. Test System

Guideline Criteria	Reported Information
Source of dilution water Soft reconstituted water or water from a natural source, not dechlorinated tap water	Carbon filtered dechlorinated tap water
Does water support test animals without observable signs of stress?	Yes
Water Temperature 17°C or 22°C	23 °C
pH Prefer 7.2 to 7.6	7.6 - 8.4
Dissolved Oxygen Static: ≥ 60% during 1 st 48 hrs and ≥ 40% during 2 nd 48 hrs, flow-through: ≥ 60%	≥87% of saturation during the test
Total Hardness Prefer 40 to 200 mg/L as CaCO ₃	164 mg/L as CaCO ₃
Test Aquaria 1. Material: Glass or stainless steel 2. Size: Volume of 18.9 L (5 gal) or 30 x 60 x 30 cm 3. Fill volume: 15-30 L of solution	Glass 20-L 15 L
Type of Dilution System Must provide reproducible supply of toxicant	N/A
Flow Rate	N/A

Guideline Criteria	Reported Information
<u>Biomass Loading Rate</u> Static: ≤ 0.8 g/L at $\leq 17^{\circ}\text{C}$, ≤ 0.5 g/L at $> 17^{\circ}\text{C}$; flow-through: ≤ 1 g/L/day	0.50 g/L
<u>Photoperiod</u> 16 hours light, 8 hours dark	16 h light, 8 h dark
<u>Solvents</u> Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests	Solvent: none Maximum conc.: N/A

D. Test Design

Guideline Criteria	Reported Information
<u>Range Finding Test</u> If $\text{LC}_{50} > 100$ mg/L with 30 fish, then no definitive test is required.	Pretests were conducted, however, the results were not reported.
<u>Nominal Concentrations of Definitive Test</u> Control & 5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be in a geometric series	Control, 10, 18, 32, 58, and 100 mg/L
<u>Number of Test Organisms</u> Minimum 10/level, may be divided among containers	10 fish per treatment level or control
Test organisms randomly or impartially assigned to test vessels?	Yes
Biological observations made every 24 hours?	Yes

Guideline Criteria	Reported Information
<u>Water Parameter Measurements</u> 1. <u>Temperature</u> Measured constantly or, if water baths are used, every 6 hrs, may not vary > 1°C 2. <u>DO and pH</u> Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control	Temperature, DO, and pH measured daily in each control and treatment replicate
<u>Chemical Analysis</u> Needed if solutions were aerated, if chemical was volatile, insoluble, or known to absorb, if precipitate formed, if containers were not steel or glass, or if flow-through system was used	Yes, solutions collected at 0 and 96 hours were analyzed by HPLC

12. REPORTED RESULTS:

A. General Results

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes, but compliance was with OECD and Swiss GLP. A QA statement was also included in the report.
<u>Recovery of Chemical</u> 1. Percent of nominal 2. Limit of detection 3. Method validation	1. 85 - 93% 2. 1 mg/L 3. Not reported
<u>Control Mortality</u> Not more than 10% control organisms may die or show abnormal behavior.	0% control mortality

Guideline Criteria	Reported Information
Raw data included?	Yes
Signs of toxicity (if any) were described?	No signs of test material toxicity were reported

Analytical Results

Toxicant Concentration (mg/L)				
Nominal	Hour of Study		Mean Measured (SD)	Percent of Nominal
	0	96		
Control	<1	<1	-	-
10	8.50	8.80	8.70 (0.21)	87
18	16.70	16.60	16.70 (0.07)	93
32	27.20	27.20	27.20 (0.0)	85
58	54.50	52.30	53.40 (1.56)	92
100	92.50	93.70	93.10 (0.85)	93

Mortality

Concentration (ppm)		Number of Fish	Cumulative Number Dead			
Nominal	Mean Measured		Hour of Study			
			24	48	72	96
Control	-	10	0	0	0	0
10	8.7	10	0	0	0	0

Concentration (ppm)		Number of Fish	Cumulative Number Dead			
Nominal	Mean Measured		Hour of Study			
			24	48	72	96
18	16.7	10	0	0	0	0
32	27.2	10	0	0	0	0
58	53.4	10	0	0	0	0
100	93.1	10	0	0	0	0

Other Significant Results: No signs of test material toxicity were reported.

B. Statistical Results

Statistical method: Visual observation using nominal concentrations

96-hr LC_{50} : >100 ppm

95% C.I.: N/A

Probit Slope: N/A

NOEC: 100 ppm

13. VERIFICATION OF STATISTICAL RESULTS:

Parameter	Result
Binomial Test LC_{50} (C.I.)	N/A
Moving Average Angle LC_{50} (95% C.I.)	N/A
Probit LC_{50} (95% C.I.)	N/A
Probit Slope	N/A
NOEC	100 ppm (93.1 ppm mean measured concentration)

14. REVIEWER'S COMMENTS: This study is scientifically sound but does not fulfill the

guideline requirements for an acute toxicity test using a freshwater fish. The percent purity of the test material was not reported. Aeration of test dilution water was employed during study. De-chlorinated tap water was employed as dilution water. The 96-hour LC_{50} for carp was determined to be >100 ppm (>93.1 ppm mean measured concentration), which classifies CGA-51202 as practically non-toxic to the carp. The NOEC was determined to be 100 ppm (93.1 ppm mean measured concentration).

DATA EVALUATION RECORD
§ 72-2 - ACUTE EC₅₀ TEST WITH A FRESHWATER INVERTEBRATE

1. **CHEMICAL:** Metolachlor PC Code No.: 108801
2. **TEST MATERIAL:** CGA-51202 Purity: Not reported
3. **CITATION:** Author: A. Vial
Title: Report on the Acute Toxicity Test of CGA-51202 On Daphnia (*Daphnia magna* STRAUS 1820)
Study Completion Date: August 12, 1991
Laboratory: Ciba-Geigy Limited, Crop Protection Division, Basle, Switzerland
Sponsor: Novartis Crop Protection, Inc., Greensboro, NC
Laboratory Report ID: 918162
MRID No.: 449295-03
DP Barcode: D260007

4. **REVIEWED BY:** Karl Bullock, M.S., Environmental Scientist,
Golder Associates Inc.

Signature:

Date: 11/99

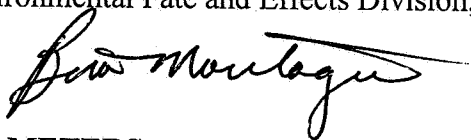
APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist,
Golder Associates Inc.

Signature:

Date:

5. **APPROVED BY:** Brian Montague, Fisheries Biologist
Environmental Fate and Effects Division, OPP

Signature:



Date: March 2000

6. STUDY PARAMETERS:

Age of Test Organism:	≤24 hours
Definitive Test Duration:	48 hours
Study Method:	Static
Type of Concentrations:	Mean measured

7. **CONCLUSIONS:** This study is scientifically sound, but does not fulfill the guideline requirements. The percent purity of the test material was not reported.

Results Synopsis

EC ₅₀ : 15.4 ppm	95% C.I.: 13.0 - 18.4 ppm
NOEC: 5.2 ppm	Probit Slope: 6.1

8. **ADEQUACY OF THE STUDY:** A. **Classification:** Supplemental.

B. Rationale: The percent purity of the test material was not reported. Hardness of 240 mg/L as CaCO₃ used in study.

C. Repairability: No-hardness too high.

9. GUIDELINE DEVIATIONS:

1. The percent purity of the test material was not reported.
2. The reported pH (7.8 -7.9) and hardness (240 mg CaCO₃/L) is higher than recommended (pH: 7.2 - 7.6; hardness: 40 - 200 mg CaCO₃/L).
3. Temperature was measured at test initiation and termination; guideline protocol recommends continuous temperature monitoring for a test system controlled by the room temperature.

10. SUBMISSION PURPOSE: To support reregistration of metolachlor products.

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
<u>Species</u> Preferred species is <i>Daphnia magna</i>	<i>Daphnia magna</i>
All organisms are approximately the same size and weight?	Not reported
<u>Life Stage</u> Daphnids: 1 st instar (<24 h)	1 st instar (≤24 h)
Supplier	In-house cultures
All organisms from the same source?	Yes

B. Source/Acclimation

Guideline Criteria	Reported Information
<u>Acclimation Period</u> Minimum 7 days	Cultures were maintained under conditions similar to testing.

Guideline Criteria	Reported Information
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	None reported
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	N/A
<u>Feeding</u> No feeding during the study.	No feeding during the study
<u>Pretest Mortality</u> No more than 3% mortality 48 hours prior to testing.	Not reported

C. Test System

Guideline Criteria	Reported Information
<u>Source of dilution water</u> Soft reconstituted water or water from a natural source, not dechlorinated tap water.	Reconstituted water prepared from bi-distilled water.
Does water support test animals without observable signs of stress?	Not reported
<u>Water Temperature</u> Daphnia: 20°C Amphipods and mayflies: 17°C Midges and mayflies: 22°C Stoneflies: 12°C	20 - 22°C
<u>pH</u> Prefer 7.2 to 7.6.	7.8 - 7.9
<u>Dissolved Oxygen</u> Static: ≥ 60% during 1 st 48 h and ≥ 40% during 2 nd 48 h, flow-through: ≥ 60%.	≥99% during the test
<u>Total Hardness</u> Prefer 40 to 200 mg/L as CaCO ₃ .	240 mg/L as CaCO ₃

Guideline Criteria	Reported Information
<u>Test Aquaria</u> 1. <u>Material</u> : Glass or stainless steel. 2. <u>Size</u> : 250 mL (daphnids and midges) or 3.9 L (1 gal). 3. <u>Fill volume</u> : 200 mL (daphnids and midges) or 2-3 L.	Glass Not reported 100 mL
<u>Type of Dilution System</u> Must provide reproducible supply of toxicant.	N/A
<u>Flow Rate</u>	N/A
<u>Biomass Loading Rate</u> Static: ≤ 0.8 g/L at $\leq 17^{\circ}\text{C}$, ≤ 0.5 g/L at $> 17^{\circ}\text{C}$; flow-through: ≤ 1 g/L/day.	1 daphnid/20 mL
<u>Photoperiod</u> 16 hours light, 8 hours dark.	16 hours light, 8 hours dark
<u>Solvents</u> Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests.	None used

D. Test Design

Guideline Criteria	Reported Information
<u>Range Finding Test</u> If $\text{EC}_{50} > 100$ mg/L, then no definitive test is required.	Results of pretests were not reported.
<u>Nominal Concentrations of Definitive Test</u> Control & 5 treatment levels; a geometric series with each concentration being at least 60% of the next higher one.	Negative control, 5.8, 10, 18, 32, and 58 mg/L, not corrected for percent purity.

Guideline Criteria	Reported Information
<u>Number of Test Organisms</u> Minimum 20/level, may be divided among containers.	20 per level, 5 per replicate
Test organisms randomly or impartially assigned to test vessels?	Yes
<u>Water Parameter Measurements</u> 1. <u>Temperature</u> Measured continuously or, if water baths are used, every 6 h, may not vary > 1°C. 2. <u>DO and pH</u> Measured at beginning of test and every 48 h in the high, medium, and low doses and in the control.	Temperature, DO, and pH were measured at test initiation and termination.
<u>Chemical Analysis</u> Needed if solutions were aerated, if chemical was volatile, insoluble, or known to absorb, if precipitate formed, if containers were not steel or glass, or if flow-through system was used	Solutions collected at 0 and 48 hours and analyzed for CGA-51202 using HPLC.

12. REPORTED RESULTS:

A. General Results

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	The study was conducted in accordance with OECD and Swiss GLP guidelines. A QA statement was also included in the report.
<u>Control Mortality</u> Static: ≤10% Flow-through: ≤5%	0% mortality in the control
Percent Recovery of Chemical 1. Percent of nominal 2. Detection limit 3. Method validation	1. Range 89 - 103% 2. 1.0 mg/L 3. Average recovery = 108.1%

Guideline Criteria	Reported Information
Raw data included?	Yes

Analytical Results

Toxicant Concentration (mg/L)				
Nominal	Hour of Study		Mean Measured (SD)	Percent of Nominal
	0	96		
Control	<1	<1	-	-
5.8	4.80	5.50	5.15 (0.49)	89
10	7.80	10.30	9.05 (1.77)	91
18	16.20	16.70	16.45 (0.35)	91
32	32.50	33.30	32.90 (0.57)	103
58	56.70	55.60	56.15 (0.78)	97

Mortality/Immobilization

Nominal Concentration (mg/L)	Mean measured Concentration (mg/L)	Number of Daphnids	Cumulative Number Immobile/Dead	
			24-hr	48-hr
Control	<1.0	20	0	0
5.8	5.15	20	0	0
10	9.05	20	1	1
18	16.45	20	12	13
32	32.90	20	17	19
58	56.15	20	20	20

Other Significant Results: No sublethal signs of toxicity were reported.

B. Statistical Results: Results based on nominal concentrations. Method: Probit

48-hr EC₅₀: 16.6 mg/L 95% C.I.: 14.2 - 19.4 mg/L
 Probit Slope: N/R NOEC: 5.8 mg/L

13. VERIFICATION OF STATISTICAL RESULTS:

Method: Probit analysis using mean measured concentrations

48-hr EC₅₀: 15.4 ppm 95% C.I.: 13.0 - 18.4 ppm
 Probit Slope: 6.1 NOEC: 5.2 ppm

- 14. REVIEWER'S COMMENTS:** This study is scientifically sound but does not fulfill the guideline requirements, and is classified as **Supplemental**. The percent purity of the test substance was not reported. The hardness of the test dilution water was above recommended limits for OECD and USEPA testing requirements which may effect the chemical characteristics and toxicity of the test material. The EC50 for daphnia exposed to CGA-51202 was determined to be 15.4 ppm, which classifies CGA-51202 as slightly toxic to the daphnid. The NOEC was determined to be 5.2 ppm.

9. **GUIDELINE DEVIATIONS:** No deviations of consequence were noted.

10. **SUBMISSION PURPOSE:** Submitted to support reregistration.

11. **MATERIALS AND METHODS:**

A. Test Organisms

Guideline Criteria	Reported Information
Species 6 dicots in 4 families, including soybean and a rootcrop; 4 monocots in 2 families, including corn.	<u>Dicots</u> : cabbage, carrot, cucumber, lettuce, soybean, tomato <u>Monocots</u> : corn, oat, onion, ryegrass
Number of plants per rep At least 5	6 for cabbage, carrot, and lettuce, and 5 for the remaining 7 species
Source of Seed	Commercial suppliers

B. Test System

Guideline Criteria	Reported Information
Solvent	None
Site of test	Greenhouse
Planting method / type of pot	Planted within 24 hours prior to application/10-cm square pots
Method of application	Spray booth
Method of watering	Hand watered avoiding foliage
Growth stage at application 1-3 true leaf stage	2-4 true leaf stage

C. Test Design

Guideline Criteria	Reported Information
Dose range 2x or 3x	N/A
Doses At least 5	0.5 lb active ingredient (ai)/A
Controls Negative and solvent	Deionized well water and formulation blank (water) control groups
Replicates per dose At least 3	4 replicates
Duration of test 14 days	3 weeks
Were observations made at least weekly?	Yes
Maximum labeled rate	0.5 lb ai/A

12. REPORTED RESULTS:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Was an NOEL observed for each species?	Only for certain species-others unaffected
Phytotoxic observations	Yes
Were initial chemical concentrations measured? (Optional)	No
Were adequate raw data included?	Yes

Results for the most sensitive parameter of each species*

Species	Parameter	Inhibition (%)
Cabbage	shoot length	2
Cucumber	no parameter inhibited	N/A
Lettuce	no parameter inhibited	N/A
Carrot	no parameter inhibited	N/A
Soybean	no parameter inhibited	N/A
Tomato	no parameter inhibited	N/A
Corn	dry weight	2
Oat	shoot length	4
Onion	no parameter inhibited	N/A
Ryegrass	shoot length	1

*The most sensitive parameter is based on percent inhibition.

Observations: No visual phytotoxicity signs were observed on any of the tested species.

Statistical Method: Analysis of variance was conducted for each species parameter. It was stated that effects on measured parameters were less than 25% for all species.

13. **VERIFICATION OF STATISTICAL RESULTS:** No statistical analysis was performed since the highest inhibition was only 4% when compared to the controls.
14. **REVIEWER'S COMMENTS:** This study is scientifically sound, fulfills the guideline requirements, and can be classified as **Core**.

**DATA EVALUATION RECORD
SEEDLING EMERGENCE TIER I TEST
§ 122-1**

1. **CHEMICAL:** Metolachlor PC Code No.: 108801
2. **TEST MATERIAL:** CGA-51202 Purity: 99.9%
3. **CITATION:** Author: D. Schwab
Title: Evaluating the Effects of CGA-51202 on the Emergence and Vegetative Vigor of Non-Target Terrestrial Plants
Study Completion Date: November 13, 1997
Laboratory: ABC Laboratories, Inc., Columbia, MO
Sponsor: Novartis Crop Protection, Inc., Greensboro, NC
Laboratory Study ID: 43901
MRID No.: 449295-13
DP Barcode: D260009

4. **REVIEWED BY:** Karl Bullock, M.S., Environmental Scientist,
Golder Associates Inc.

Signature:

Date:

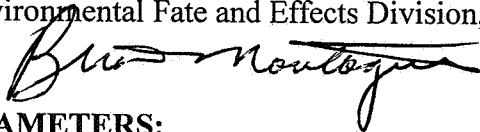
APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist
Golder Associates Inc.

Signature:

Date:

5. **APPROVED BY:** Brian Montague, Fisheries Biologist
Environmental Fate and Effects Division, OPP

Signature:



Date: March 2000

6. **STUDY PARAMETERS:**

Definitive Study Duration: 21 days

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for a seedling emergence study with terrestrial plants. None of the ten test species exposed to the maximum labeled rate of CGA-51202 (0.5 lb ai/A) were affected by 25% when compared to the pooled controls for each measured parameter.

Results Synopsis:

EC25 > 0.5 lb ai/A **NOEL** (onion, corn, tomato, cucumber) < 0.5 lbs ai/A

8. **ADEQUACY OF THE STUDY:**

A. **Classification:** Core.

B. **Rationale:** N/A.

C. **Repairability:** N/A.

9. **GUIDELINE DEVIATIONS:** The organic matter content of the soil (2.7%) was greater than recommended (1.0%).

10. **SUBMISSION PURPOSE:** Submitted to support reregistration.

11. **MATERIALS AND METHODS:**

A. Test Organisms

Guideline Criteria	Reported Information
Species 6 dicots in 4 families, including soybean and a rootcrop; 4 monocots in 2 families, including corn.	<u>Dicots:</u> cabbage, carrot, cucumber, lettuce, soybean, tomato <u>Monocots:</u> corn, oat, onion, ryegrass
Number of seeds per rep 10	10
Source of Seed	Commercial suppliers
Historical % Germination of Seed	≥85%

B. Test System

Guideline Criteria	Reported Information
Solvent	Deionized water
Site of test	Greenhouse
Planting method / type of pot	Planted within 24 hours prior to application/10-cm square pots
Method of application	Spray application
Method of watering	Watered by hand
Growth stage at application Seed or plant.	Seed

C. Test Design

Guideline Criteria	Reported Information
Dose range 2x or 3x	N/A
Doses At least 5	Single at 0.5 lb ai/A
Controls Negative and solvent	Deionized well water and formulation blank (water) control groups
Replicates per dose At least 3	4 replicates
Duration of test 14 days	3 weeks
Were observations made at least weekly?	Yes
Maximum labeled rate	0.5 lb ai/A

12. REPORTED RESULTS:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Was an NOEL observed for each species?	No 25 % effects at up to 0.5 lb ai/A equivalent
Phytotoxic observations	No phytotoxic effects were noted in any of the test species
Were initial chemical concentrations measured? (Optional)	Yes, 95 - 98% of nominal
Were adequate raw data included?	Yes

Results for the most sensitive parameter of each species*

Species	Parameter	Inhibition (%)
Cabbage	emergence	3
Carrot	No parameter affected	0
Cucumber	shoot length	7
Lettuce	emergence	1
Soybean	dry weight	4
Tomato	dry weight	8
Corn	dry weight	6
Oat	No parameter affected	0
Onion	emergence	21
Ryegrass	emergence	1

*The most sensitive parameter is based on percent inhibition and comparisons were made to the pooled control group.

Observations: None of the ten test species were affected by treatment based on phytotoxicity observations.

Statistical Method: Analysis of variance was conducted for each species parameter. It was stated that effects on measured parameters were not greater than 25%.

13. **VERIFICATION OF STATISTICAL RESULTS:** Comparisons were made between the formulation control group and the treatment group for all parameters. None of the measured parameters were affected by 25% or more.
14. **REVIEWER'S COMMENTS:** The organic matter content of the soil used in the study was reported to be 2.7%. The maximum organic matter content suggested by EPA for a seedling emergence test is 1%. This study is scientifically sound and fulfills the guideline requirements. The study is classified as **Core**.

**DATA EVALUATION RECORD
AQUATIC PLANT EC₅₀ TEST
GUIDELINE 123-2 (TIER II)**

1. **CHEMICAL:** Metolachlor PC Code No.: 108801
2. **TEST MATERIAL:** CGA-51202 Purity: >99.9%

3. **CITATION:**

Authors: R.L. Boeri, J.P. Magazu, and T.J. Ward
Title: Acute Toxicity of CGA-51202 to the Duckweed, *Lemna gibba* G3
Study Completion Date: September 18, 1997
Laboratory: T.R. Wilbury Laboratories, Inc., Marblehead, MA
Sponsor: Novartis Crop Protection, Greensboro, NC
Laboratory Report ID: 1233-NO
MRID No.: 449295-14
DP Barcode: D260010

4. **REVIEWED BY:** Karl Bullock, M.S., Environmental Scientist,
Golder Associates Inc.

Signature:

Date: 11/10/99

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist,
Golder Associates Inc.

Signature:

Date:

5. **APPROVED BY:** Brian Montague, Fisheries Biologist
Environmental Fate and Effects Division, OPP

Signature:



Date: April 2000

6. **STUDY PARAMETERS:** **Definitive Test Duration:** 14 days
Type of Concentrations: Initial measured

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an aquatic plant toxicity test.

Results Synopsis:

EC₅₀: >95.4 ppm ai

95% C.I.: N/A

NOEC: 95.4 ppm ai

Probit Slope: N/A

8. **ADEQUACY OF THE STUDY:** A. **Classification:** Core.

B. **Rationale:** Fulfills guideline requirements.

C. **Repairability:** N/A

8. ADEQUACY OF THE STUDY:**A. Classification:** Core.**B. Rationale:** Fulfills guideline requirements.**C. Repairability:** N/A**9. GUIDELINE DEVIATIONS:** The maximum label rate was not reported.**10. SUBMISSION PURPOSE:****11. MATERIALS AND METHODS:****A. Test Organisms**

Guideline Criteria	Reported Information
<u>Species</u> <i>Lemna gibba</i>	<i>Lemna gibba</i>
<u>Number of Plants/Fronds</u> 5 plants, 3 fronds each	3 plants, 3-4 fronds each, total of 11-12 fronds per replicate
<u>Nutrients</u> Standard formula, e.g. 20XAAP	M-Hoagland's medium without sucrose or EDTA

B. Test System

Guideline Criteria	Reported Information
<u>Solvent</u>	None
<u>Temperature</u> 25°C	23.0 - 24.6°C
<u>Light Intensity</u> 5.0 KLux ($\pm 15\%$)	5.4 KLux
<u>Photoperiod</u> Continuous	Continuous
<u>Test System</u> Static or Renewal	Static
<u>pH</u> Approx. 5.0	Initial: 3.7 - 4.9 Final: 5.7 - 6.2

C. Test Design

Guideline Criteria	Reported Information
<u>Dose range</u> 2X or 3X progression	2X
<u>Doses</u> at least 5	6.0, 13, 25, 50, and 100 mg ai/L
<u>Controls</u> negative and/or solvent	Negative control
<u>Replicates per dose</u> 3 or more	3
<u>Duration of test</u> 14 days	14 days
Daily observations were made?	Counts and observations made on days 1, 4, 6, 8, 11, 13, and 14
<u>Method of Observations</u>	Number of normal and chlorotic fronds
<u>Maximum Labeled Rate</u>	Not reported

12. REPORTED RESULTS:

Guideline Criteria	Reported Information
Initial and 14 day frond numbers were measured?	Yes
Control frond at 14 days \geq2X initial count?	Yes
Initial chemical concentrations measured? (Optional)	Samples were collected at initiation and termination and analyzed by HPLC.
Raw data included?	Yes

Analytical Results

Nominal	Toxicant Concentration (mg/L)			
	Hour of Study		Mean Measured (SD)	Percent of Nominal
	0	96		
Control	<2.00	<2.00	-	-
6.0	5.25	2.80	4.0 (1.73)	67
13	12.2	6.33	9.3 (4.15)	72
25	24.6	17.5	21.1 (5.02)	84
50	46.9	37.1	42.0 (6.93)	84
100	95.4	82.2	88.8 (9.33)	89

Dose Response

Initial Measured concentration (ppm ai)	14-day Avg. Number of Normal Fronds	% Inhibition*	14-day pH
Control	142	N/A	6.0
5.25	138	2.8	6.1
12.2	149	-4.9	6.2
24.6	140	1.4	6.2
46.9	133	6.3	6.1
95.4	146	-2.8	5.9

* Compared to the control; negative sign indicates stimulation.

Other Significant Results: No sublethal effects were observed other than the presence of a small number of chlorotic fronds in the control and all treatment groups. No flowers were noted in any group.

Statistical Results:

Statistical Methods: Visual observation for EC₅₀; analysis of variance coupled with Dunnett's test for NOEC.

EC₅₀: >95.4 ppm ai

95% C.I.: N/A

Probit Slope: N/A

NOEC: 95.4 ppm ai

13. VERIFICATION OF STATISTICAL RESULTS: Williams' test was used to confirm the NOEC. The EC₅₀ value could not be calculated because there was at least 94% of the control growth at all tested concentrations.

EC₅₀: >95.4 ppm ai

95% C.I.: N/A

Probit Slope: N/A

NOEC: 95.4 ppm ai

14. REVIEWER'S COMMENTS: Although the maximum label rate of the test material was not reported, the reviewer believed that it was probably well below 130 lb ai/A (the rate which would result in an aquatic concentration of 95.4 ppm ai when applied on the surface of a 15-cm deep water body).

This study is scientifically sound, fulfills the guideline requirements, and can be classified as **Core**. Based on initial measured concentrations, the EC₅₀ was determined to be >95.4 ppm ai, the highest concentration tested. The NOEC was determined to be 95.4 ppm ai.

CGA-51202: Acute Lemna - Growth
 File: 44929514 Transform: NO TRANSFORM

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	Control	3	142.333	142.333	140.000
2	5.25	3	137.667	137.667	140.000
3	12.2	3	149.000	149.000	140.778
4	24.6	3	140.333	140.333	140.778
5	46.9	3	133.000	133.000	140.778
6	95.4	3	146.000	146.000	146.000

CGA-51202: Acute Lemna - Growth
 File: 44929514 Transform: NO TRANSFORM

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
Control	140.000				
5.25	140.000	0.125		1.78	k= 1, v=12
12.2	140.778	0.083		1.87	k= 2, v=12
24.6	140.778	0.083		1.90	k= 3, v=12
46.9	140.778	0.083		1.92	k= 4, v=12
95.4	146.000	0.196		1.93	k= 5, v=12

s = 22.902

Note: df used for table values are approximate when v > 20.

**DATA EVALUATION RECORD
ALGAE OR DIATOM EC₅₀ TEST
GUIDELINE 123-2 (TIER II)**

1. **CHEMICAL:** Metolachlor PC Code No.: 108801
2. **TEST MATERIAL:** CGA-51202 Purity: Not reported
3. **CITATION:** Author: A. Vial
Title: Report on the Growth Inhibition Test of CGA-51202 to Green Algae (*Scenedesmus subspicatus*)
Study Completion Date: August 12, 1991
Laboratory: Ciba-Geigy Ltd., Crop Protection Division, Basle, Switzerland
Sponsor: Novartis Crop Protection, Inc., Greensboro, NC
Laboratory Project ID: 918152
DP Barcode: D260010
MRID No.: 449295-15
4. **REVIEWED BY:** Karl Bullock, M.S., Environmental Scientist,
Golder Associates Inc.

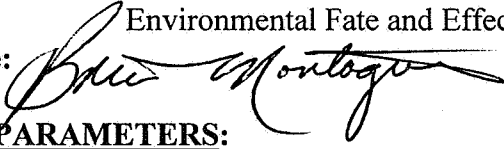
Signature:

Date: 11/10/99

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist,
Golder Associates Inc.

Signature:

Date:
5. **APPROVED BY:** Brian Montague, Fisheries Biologist
Environmental Fate and Effects Division, OPP

Signature: 

Date: April 2000
6. **STUDY PARAMETERS:**

Definitive Test Duration:

72 hours

Type of Concentrations:

Initial measured
7. **CONCLUSIONS:** This study is scientifically sound but does not fulfill the guideline requirements for a Tier-II algal toxicity test. The percent purity of the test substance was not reported, and the test was conducted for only 3 days.
Results Synopsis
72-hour EC₅₀ = 57.1 (29.3 to inf.) NOEC 29.3 ppm Slope = N/A
8. **ADEQUACY OF THE STUDY:**
A. **Classification:** Supplemental.

DATA EVALUATION RECORD
ALGAE OR DIATOM EC₅₀ TEST
GUIDELINE 123-2 (TIER II)

1. **CHEMICAL:** Metolachlor **PC Code No.:** 108801
2. **TEST MATERIAL:** CGA-51202 **Purity:** Not reported

3. **CITATION:**

Author: A. Vial
Title: Report on the Growth Inhibition Test of
CGA-51202 to Green Algae (*Scenedesmus*
subspicatus)
Study Completion Date: August 12, 1991
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Sponsor: Novartis Crop Protection, Inc.,
Greensboro, NC
Laboratory Project ID: 918152
DP Barcode: D260010
MRID No.: 449295-15

4. **REVIEWED BY:** Karl Bullock, M.S., Environmental Scientist,
Golder Associates Inc.

Signature: *Karl Bullock* **Date:** 11/10/99

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist,
Golder Associates Inc.

Signature: *P. Kosalwat* **Date:** 11/10/99

5. **APPROVED BY:** Kevin Costello

Signature: **Date:**

6. **STUDY PARAMETERS:**

Definitive Test Duration: 72 hours
Type of Concentrations: Initial measured

7. **CONCLUSIONS:** This study is scientifically sound but does not fulfill the guideline requirements for a Tier-II algal toxicity test. The percent purity of the test substance was not reported, and the test was conducted for only 3 days. The 72-hour EC₅₀ and NOEC for *S. subspicatus* exposed to CGA-51202 were 57.1 and 29.3 ppm, respectively.

8. ADEQUACY OF THE STUDY:**A. Classification:** Supplemental.**B. Rationale:** The percent purity of the test substance was not reported and the test was conducted for only 3 days.**C. Repairability:** No.**9. GUIDELINE DEVIATIONS:**

1. The percent purity of the test substance was not reported.
2. The study was conducted for 3 days rather than the required 4 days.
3. The maximum labelled rate was not reported.
4. The nutrients used in the test were not reported.

10. SUBMISSION PURPOSE:**11. MATERIALS AND METHODS:****A. Test Organisms**

Guideline Criteria	Reported Information
<u>Species</u> <i>Skeletonema costatum</i> <i>Anabaena flos-aquae</i> <i>Selenastrum capricornutum</i> <i>Navicula pelliculosa</i>	<i>Scenedesmus subspicatus</i>
<u>Initial Number of Cells</u> 3,000 - 10,000 cells/mL	9,400 cells/mL
<u>Nutrients</u> Standard formula, e.g. 20XAAP	Not reported

B. Test System

Guideline Criteria	Reported Information
<u>Solvent</u>	None
<u>Temperature</u> Skeletonema: 20°C Others: 24-25°C	23 ±1°C
<u>Light Intensity</u> Anabaena: 2.0 KLux (±15%) Others: 4.0-5.0 KLux (±15%)	10.8 KLux
<u>Photoperiod</u> Skeletonema: 14 h light, 10 h dark or 16 h light, 8 h dark Others: Continuous	Continuous
<u>pH</u> Skeletonema: approx. 8.0 Others: approx. 7.5	Initial: 6.7-7.9 Final: 7.6-7.9

C. Test Design

Guideline Criteria	Reported Information
<u>Dose range</u> 2X or 3X progression	3X
<u>Doses</u> at least 5	1.23, 3.7, 11, 33, and 100 mg/L, not corrected for percent active ingredient
<u>Controls</u> negative and/or solvent	Negative control group
<u>Replicates per dose</u> 3 or more	6 replicates in the control and 3 replicates per treatment
<u>Duration of test</u> 120 hours	72 hours
Daily observations were made?	Yes
<u>Method of Observations</u>	"TOA" cell counter
<u>Maximum Labeled Rate</u>	Not reported

12. REPORTED RESULTS:

Guideline Criteria	Reported Information
Initial and 72 h cell densities were measured?	Yes
Control cell count at 72 hr $\geq 2X$ initial count?	Yes
Initial chemical concentrations measured? (Optional) 1. Percent of nominal 2. Detection limit 3. Method validation	1. 89 - 95% of nominal 2. <1.0 mg/L 3. 108.1% of nominal
Raw data included?	Yes

Analytical Results

Toxicant Concentration (mg/L)				
Nominal	Hour of Study		Mean Measured (SD)	Percent of Nominal
	0	96		
Control	<1.0	<1.0	-	-
1.23	1.1	1.0	1.1 (0.07)	85
3.7	3.5	3.5	3.5 (0)	95
11	10.4	10.3	10.4 (0.07)	94
33.0	29.3	32.2	30.8 (2.05)	93
100.0	92.2	81.7	87.0 (7.42)	87

Dose Response

Initial Measured Concentration (ppm)	72-hour Avg. Cell Density ($\times 10^4$ cells/mL)	Inhibition* (%)	Final pH
Control	146.4	-	7.9
1.1	155.3	-6.1	7.9
3.5	154.7	-5.7	7.9
10.4	168.0	-14.8	7.9
29.3	174.0	-18.9	7.9
92.2	8.8	94.0	7.6

*Negative inhibition indicates stimulation

Other Significant Results: None.

Statistical Results for Cell Density:

Statistical Methods: The EC_{50} values were calculated according to Berkson (1953); NOEC calculated according to the modified Dunnett's test. Results are based on nominal concentrations and areas under the growth curves.

EC_{50} : 77.6 mg/L

95% C.I.: 73.1-80.8 mg/L

Probit Slope: N/A

NOEC: 33 mg/L

13. VERIFICATION OF STATISTICAL RESULTS:

Statistical Methods: Analyses were based on initial measured concentrations and cell density. The probit method could not be used since it requires at least two concentrations at which the percent inhibition is between 0 and 100. Non-linear regression could not be used to estimate the EC_{50} value because it relies upon estimates generated from the probit analysis. Therefore, the EC_{50} was estimated using the binomial method, although 95% confidence intervals could not be estimated. Williams' test was used to determine the NOEC.

EC_{50} : 57.1 ppm

95% C.I.: N/A

Probit Slope: N/A

NOEC: 29.3 ppm

14. REVIEWER'S COMMENTS: This study is scientifically sound but does not fulfill the guideline requirements for an algal toxicity test. The percent purity of the test material was not reported and the test was only conducted for 3 days rather than the required 4 days. Based on initial measured concentrations, the 72-hour EC₅₀ and NOEC for *S. subspicatus* were 57.1 and 29.3 ppm, respectively. This study can be categorized as **Supplemental**.

CGA-51202: Acute Green Algae Test
 File: 44929515 Transform: NO TRANSFORM

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	Control	6	146.417	146.417	157.472
2	1.1	3	155.333	155.333	157.472
3	3.5	3	154.667	154.667	157.472
4	10.4	3	168.000	168.000	157.472
5	29.3	3	174.000	174.000	157.472
6	92.2	3	8.833	8.833	8.833

CGA-51202: Acute Green Algae Test
 File: 44929515 Transform: NO TRANSFORM

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
Control	157.472				
1.1	157.472	0.574		1.75	k= 1, v=15
3.5	157.472	0.574		1.84	k= 2, v=15
10.4	157.472	0.574		1.87	k= 3, v=15
29.3	157.472	0.574		1.88	k= 4, v=15
92.2	8.833	7.149	*	1.89	k= 5, v=15

s = 27.219

Note: df used for table values are approximate when v > 20.

EPA PROBIT ANALYSIS PROGRAM
 USED FOR CALCULATING EC VALUES
 Version 1.4

Karl Bullock Metolachlor Scenedesmus subspicatus 10-26-99

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
92.2	100	94	94	0
29.3	100	0	0	0
10.4	100	0	0	0
3.5	100	0	0	0
1.1	100	0	0	0

BECAUSE THE NUMBER OF ORGANISMS USED WAS SO LARGE, THE 95 PERCENT
 CONFIDENCE INTERVALS CALCULATED FROM THE BINOMIAL PROBABILITY ARE
 UNRELIABLE. USE THE INTERVALS CALCULATED BY THE OTHER TESTS.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 57.07435

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE
 PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE
 NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.
